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Docket No. ORT-1548

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : SCHULTZ, T. et al.  
Serial No. : 10/022,138  
Filed : December 13, 2001  
Title : Steroid Hormone Products and Methods for Preparing Them  
Art Unit : 1616  
Examiner : Qazi, S.

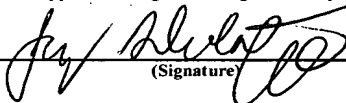
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March 22, 2004

(Date of Deposit)

Joseph S. Kentoffio

(Name of applicant, assignee, or Registered Representative)



(Signature)

March 22, 2004

(Date of Signature)

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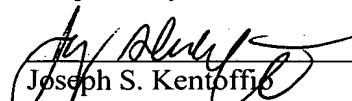
APPEAL BRIEF TRANSMITTAL

Dear Sir:

Enclosed is an Appeal Brief for the above-referenced patent application.

Please charge Deposit Account No. 10-0750/ORT-1548/JSK in the name of Johnson  
& Johnson for the cost of filing this Appeal Brief. Three copies of this Transmittal are  
enclosed.

Respectfully submitted,

  
Joseph S. Kentoffio  
Reg. No. 33,189  
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DATE: March 22, 2004



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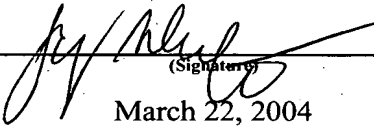
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ATTENTION: BOARD OF PATENT APPEALS AND INTERFERENCES

APPELLANTS' BRIEF PURSUANT TO 37 C.F.R. § 1.192

Dear Sir:

This is an appeal from the Final Rejection of October 21, 2003, a Notice of Appeal having been received by the USPTO on January 22, 2004. Appellants' Brief is being submitted on March 22, 2004.

The fees required under 37 C.F.R. § 1.17(f), and any required petition for extension of time for filing this brief and fees therefore, are addressed in the accompanying TRANSMITTAL OF APPEAL BRIEF.

Pursuant to 37 C.F.R. § 1.192(a), this brief is transmitted in triplicate.

REAL PARTY IN INTEREST

The real party in interest of the above-referenced patent application is Ortho-McNeil Pharmaceutical, Inc., having a principal place of business at Route 202, Raritan, NJ 08869.

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#### RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences pending.

#### STATUS OF CLAIMS

Claims 1-8 stand rejected under 35 U.S.C. § 102(a) and, in the alternative, under § 103(b), in view of US Patent No. 5,858,405 (hereinafter "Gast").

#### STATUS OF AMENDMENTS

The claims stand amended as set forth in the Response To Office Action filed on July 28, 2003.

#### SUMMARY OF THE INVENTION

The present invention provides a steroid hormone product having an improved dissolution profile and release rate profile. The product comprises at least one steroid hormone in substantially non-crystalline form in admixture with primary excipient. The excipient stabilizes the steroid in its substantially non-crystalline form. The hormone products taught by the invention are characterized by highly favorable dissolution properties. The preferred excipient for stabilizing the steroid in its non-crystalline form is lactose. The steroid hormone products of the invention are particularly useful as either oral contraceptives or HRT products.

#### STATEMENT OF ISSUES

Whether claims 1-8 are anticipated by US Patent No. 5, 858,405, i.e., whether this reference discloses each and every aspect of the claimed invention.

Whether claims 1-8 are obvious over US Patent No. 5, 858,405, i.e., whether a person skilled in the art would be lead by the teachings of the Gast reference to prepare the claimed invention.

#### GROUPING OF CLAIMS

For the purposes of this Appeal, all of the pending claims 1-8 stand or fall together.

## ARGUMENTS

Claims 1-8 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Gast or, in the alternative, under 35 U.S.C. § 103(a) as unpatentable over Gast. The Examiner argues that Gast teaches a hormonal product which “embraces” applicants’ claimed invention. In particular, the Examiner points to the examples, the claims and column 7, lines 11-19 and lines 31-67 of this reference. Applicants request that the rejection be overturned since Gast neither teaches nor suggests the claimed invention.

Gast is not directed to steroid hormone formulations having improved dissolution and release rate properties. Rather, Gast provides a novel tri-phasic regimen for administering oral contraceptives, wherein a combination of an estrogen and a progestin are administered for 23-25 days followed by 3-5 days of estrogen-only administration. Gast’s formulations include a progestin and an estrogen and further include components such as colorants, lubricants, fillers and the excipient lactose. All of these components are well known in the art of formulating oral contraceptives. The novel aspects of Gast are directed to the dosages of the specified hormones and the particular tri-phasic contraceptive regimen taught by Gast.

Gast nowhere teaches a formulation wherein the steroid hormone in the formulation is in non-crystalline form and wherein the hormone is stabilized in this form by the excipient. Instead, and as specifically pointed out by Gast at column 9, line 67 to column 10, line 1, the formulations set forth in his Examples 1 and 2 are prepared by conventional methodology well known to those skilled in the art. Since Gast fails to teach each and every aspect of the claimed steroid hormone products, this reference cannot form the basis of a rejection under 35 U.S.C. § 102(b). MehlBiophile International Corp. v. Milgraum, 52 USPQ 2d 1303, 1306 (Fed. Cir. 1999). Accordingly, applicants request that the Board overturn this rejection.

The Examiner further argues that it would be obvious to prepare the claimed products based on the teachings of the Gast reference. In this connection, the Examiner argues that since claim 1 includes the term “comprising” the claims are open ended and do not preclude the inclusion of unrecited elements or method steps. The Examiner’s reliance on this argument and the attendant case law cited in support of this point is not understood.

The fact that the claimed product could include additional elements does not cure the fundamental shortcoming of the Gast reference, namely, the lack of any teaching or suggestion that the steroid hormone is in non-crystalline form and that the hormone is stabilized in this form by the excipient.

Wet processing techniques commonly employed for making commercial quantities of steroid hormone products, such as oral contraceptives, are disclosed at pages 1-3 of the instant specification. Since Gast provides no teaching or suggestion to the contrary, it may be surmised that these well known processes are the "conventional methodology" Gast refers to for making the formulations set forth in his examples. The disadvantages presented by steroid hormone formulations prepared by wet processing are set forth on pages 3-4 of the specification. Even if the formulations exemplified in Gast were made according to the dry process proposed in US Patent No. 5,858,405, and described at page 3 of the instant specification, the formulations would still present disadvantages such as the existence of multiple polymorphic forms, variability in release rate and poorly reproducible dissolution profiles.

In the case of the claimed products, at least one steroid hormone is mixed with an excipient, preferably lactose, such that sufficient mechanical energy is imparted to the mixture to produce an hormone/excipient powder blend in which the steroid hormone is stabilized by the excipient in non-crystalline form. No such process is disclosed by Gast for making a steroid hormone product, nor does Gast suggest any other process methodology that would yield the claimed product. Accordingly, the only manner in which the claimed product could be derived from Gast is by applying applicants' own teachings to the Gast disclosure. Such hindsight reconstruction of the invention based on reading applicants' own teachings into the prior art is clearly impermissible. In re Dembiczak, 50 USPQ 2d 1614, 1617 (Fed. Cir. 1999). Accordingly, applicants request that the rejection issued under 35 U.S.C. § 103(a) be overturned.

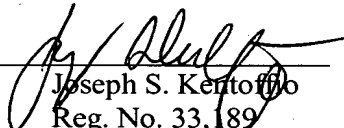
In view of the foregoing, appellants request that the Examiner's Final Rejection be overturned and that this application be passed to allowance at the earliest possible date.

Please charge the fee of \$330.00 required under 37 C.F.R § 1.17(c), any deficiency in this fee and any other fees that may be required in connection with the filing of appellants' Appeal Brief to Deposit Account No. 10-0750/ORT-1548/JSK.

Appellants' Appeal Brief is being filed in triplicate.

Respectfully submitted,

By: \_\_\_\_\_

  
Joseph S. Kento  
Reg. No. 33,189

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(732) 524-3711  
Dated: March 22, 2004

## **APPENDIX OF CLAIMS**

1. A steroid hormone product having improved dissolution and release rate properties, said product comprising a steroid hormone in admixture with an excipient, wherein substantially all of said steroid hormone is in non-crystalline form and wherein said excipient stabilizes said hormone in its non-crystalline form.
2. The steroid hormone product of claim 1, wherein the primary excipient is selected from the group consisting of dextrose, fructose, sorbitol, xylitol, sucrose, lactose, mannitol, dextrate, cellulose, starch and mixtures thereof.
3. The steroid hormone product of claim 1 wherein the steroid hormone is at least one of a progestin and an estrogen
4. The steroid hormone product of claim 3, wherein the steroid hormone is a progestin selected from the group consisting of norgestimate, norgestrel, levonorgestrel, norethindrone and desogestrel.
5. The steroid hormone product of claim 4 wherein the steroid hormone is norgestimate and the excipient is lactose.
6. The steroid hormone product of claim 3, wherein the product is one of an oral contraceptive product and a hormone replacement therapy product.
7. The steroid hormone product of claim 6, wherein the product is an oral contraceptive product comprising from about 10  $\mu\text{g}$  to about 50  $\mu\text{g}$  of an estrogen and/or from about 50  $\mu\text{g}$  to about 300  $\mu\text{g}$  of a progestin.
8. The steroid hormone product of claim 7, wherein the progestin is norgestimate and the excipient is lactose.